RESPONSE

I. Status of the Claims

Prior to the Requirement, claims 3-12, 25, 29-31, 34-39, 41, 42 and 46 were pending. Presently, claim 47 has been added, which is fully supported by the specification. No claims have been amended or cancelled. According to 37 C.F.R. § 1.121(c), a copy of the pending claims is provided in the amendment section.

Claims 3-12, 25, 29-31, 34-39, 41, 42, 46 and 47 are therefore pending in the case, each of which read on the invention elected with traverse.

II. Support for the Claims

Support for the new claim exists throughout the specification and claims of the original and parent applications. Any fee due for the new claim should be deducted from Peregrine Pharmaceuticals, Inc. Deposit Account No. 50-3493/3999.002587.

New claim 47 recites that the administered immunoconjugate localizes to the vasculature and stroma of the vascularized tumor. This is supported throughout the original specification, such as, *e.g.*, first at page 13, lines 12-13 and continuing thereafter, and in the working examples, such as Example I, Example III and Example XIV. It will therefore be understood that no new matter is included in the new claim.

III. Amendment to Title

The title of this divisional application is presently being amended so that it better matches the invention claimed when the divisional application was filed. Support for the amendment to the title exists throughout the original specification and in the pending claims. It will be understood that no new matter is included by the amendment. The amendment to the title is therefore properly enterable.

IV. Restriction Requirement

The Requirement takes the position that the pending claims are drawn to two distinct inventions, set forth as:

Group I: Claims 3, 5-12, 25, 29-31, 34-39, 41, 42 and 46, said to be drawn to methods for treating cancer by administering an immunoconjugate of the claimed anti-VEGF antibody, thereby localizing the immunoconjugate to the *vasculature* of the vascularized solid tumor; classified in class 424, subclass 130.1; and

Group II: Claims 4-12, 25, 29-31, 34-39, 41, 42 and 46, said to be drawn to methods for treating cancer by administering an immunoconjugate of the claimed anti-VEGF antibody, thereby localizing the immunoconjugate to the *stroma* of the vascularized solid tumor; also classified in class 424, subclass 130.1.

Although the Requirement states that the inventions of Groups I and II are distinct "because of the following reasons", no actual reasons are set forth (Requirement at page 2). Rather, this section of the Requirement simply continues to paraphrase claims 3 and 4. The Requirement then alleges that "searching the inventions I and II together would pose an undue search burden" (Requirement at page 2), although no explanation is provided.

V. Traversal

As set forth in the MPEP, every requirement to restrict has two aspects: (A) the reasons (as distinguished from the mere statement of conclusion) why each invention as claimed is either independent or distinct from the other(s); and (B) the reasons why there would be a serious burden on the examiner if restriction is not required. MPEP 808; MPEP August 2005, at page 800-50, column 2. The present Requirement has not provided adequate reasons why the proposed inventions are distinct; and has not provided adequate reasons why there would be a serious burden on the examiner if restriction is not required.

In addition, the Requirement has failed to establish a search burden; has attempted to restrict claims that are in the same class and subclass; has overlooked the important and unifying patentable features of the claims; has ignored proper linking claims; has overlooked the specification; and is inconsistent with earlier findings of the Office, particularly in the parent patent. The Requirement is therefore improper and Applicants respectfully traverse.

As to the required reasons for distinctness, the Requirement does not give any *reasons* why the inventions of Groups I and II are believed to be distinct, but only re-states the proposed restriction and paraphrases claims 3 and 4. Such a "mere statement of conclusion" is inadequate. MPEP 808 and 808.01; MPEP August 2005, at pages 800-50 and 800-51.

The Requirement also fails to establish a serious burden on the examiner if restriction is not required, contrary to MPEP 808 and 808.02; MPEP August 2005, at pages 800-50 through 800-52. In addition to each of Groups I and II being classified in the same class and subclass, the Requirement has overlooked the important and unifying patentable feature of the claims. The patentable feature of the presently claimed invention is not treating cancer by localizing prodrug therapy to tumor vasculature or to tumor stroma, but doing so using an anti-VEGF antibody that binds to substantially the same epitope as the deposited monoclonal antibody 2C3 (claim 5). Thus, there is no separate status in the art or different fields of search, as the search is directed to an anti-VEGF antibody that binds to substantially the same epitope as the deposited monoclonal antibody 2C3.

Accordingly, claims 3 and 4 do not represent separately patentable inventions, but embodiments of a generic invention unified by proper linking claims. Moreover, the specification teaches that the deposited 2C3 antibody itself is capable of localizing to the vasculature *and* stroma of vascularized tumors (claim 47). See, for example, Example I, Example III and Example XIV.

The patentability of anti-VEGF antibodies that bind to substantially the same epitope as the deposited 2C3 antibody, and immunoconjugates, combinations and various methods of use, is now well established, as shown by the issuance and allowance of eight earlier patents/applications with the same specification and priority date as the present case. Moreover, the Office found no patentable distinction between targeting tumor vasculature and tumor stroma during examination of the patents that issued from the parent and numerous related applications. Notably, in the immediate parent application (now U.S. Patent No. 6,703,020), methods for localizing 2C3 immunoconjugates to the vasculature *and* stroma constituted a unified invention (see claims 3 and 4 in U.S. Patent No. 6,703,020).

Accordingly, the proposed restriction is improper and should be withdrawn.

VI. Election

Notwithstanding the foregoing reasoning, Applicants hereby elect the invention of Group II with traverse.

Irrespective of any timely resolution of the restriction issues, all claims remain pending in the case and available for rejoinder and issue upon the allowance of a generic or linking claim.

VII. Species Election Requirement for Group I

The Requirement also sets forth species election requirements that pertain to Group I alone (Requirement at page 3, Item 5, and continuing at pages 3-5). As Applicants elect Group II, the species election requirements for Group I are moot.

VIII. Allowability

As explained in the detailed remarks submitted on filing the present divisional application, all claims in this divisional are in condition for allowance, particularly as all

requirements of patentability have been addressed in the patents issued from the parent and related applications having the same specification as the present case.

IX. Conclusions

This is a complete response to the referenced Requirement. The present claims define a single invention that is in condition for allowance and an early indication to this effect is respectfully requested. Should Examiner Joyce have any questions or comments, a telephone call to the undersigned Applicants' representative is earnestly solicited.

Respectfully submitted,

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